

PRELIMINARY REMARKS

Claims 1 to 20 as set forth in Appendix I of this paper are now pending in this case. Claims 16 to 20 have been added as indicated.

Applicants have added new Claims 16 to 20 to further bring out some of the subsidiary embodiments of the dry powder defined in Claim 10 and the product comprising it which is defined in Claim 15. New Claims 16, 17 and 20 are supported by applicants' disclosure pertaining to Claims 1, 5 and 10, pertaining to Claims 4 and 10, and pertaining to Claims 1, 5 and 15, respectively. The embodiments defined in new Claims 18 and 19 are addressed on page 7, indicated lines 19 to 24, and indicated lines 35 to 39, of the application. No new matter has been added.

The Examiner reiterated the position that applicants' Claims 1 to 4, 6, 7 and 9 to 15 are unpatentable under Section 103(a) in light of the teaching of *Jensen et al.* (WO 91/06292), either when taken alone or when taken in view of the disclosure of *Horn et al.* (US 4,522,743). In this context, the Examiner *inter alia* points out that *Jensen et al.* teach a process for the preparation of water dispersible colorants -including carotenoids- in which hydrocolloids -including soybean protein- and excipients -including sucrose- are employed.

With regard to the foregoing part of the Examiner's summary of the teaching of *Jensen et al.* it is respectfully noted that *Jensen et al.* mention soybean protein as one representative within a diverse group of hydrocolloids¹⁾ encompassing at least thirteen generic groups of hydrocolloids of natural and synthetic origin which are further illustrated by numerous representatives. It is also deemed noteworthy that *Jensen et al.* enumerate the different generic groups of hydrocolloids and their representatives as equivalent. As such, the teaching of *Jensen et al.* provides nothing which would motivate a person of ordinary skill in the art to specifically select soybean proteins from the various generic groups of hydrocolloids of natural and synthetic origin and the representatives illustrating those generic groups. Moreover, the teaching of *Jensen et al.* refers to sucrose as one of two representatives for carbohydrates which can be employed as excipients²⁾ but does not mention lactose. As such, the teaching of *Jensen et al.* provides nothing which would motivate a person of ordi-

1) Cf. page 4, indicated line 35, to page 5, indicated line 9, of WO 91/06292.

2) Cf. page 5, indicated lines 19 to 22, of WO 97/06292.

nary skill in the art to specifically select lactose from the generic group of carbohydrates. At best, the teaching of *Jensen et al.* conveys to a person of ordinary skill in the art that the nature of the hydrocolloid and the nature of the carbohydrate is without consequence where the preparations of water dispersible colorants are concerned.

It is well settled that obviousness within the meaning of Section 103(a) requires more than the mere possibility to make a selection from the generic disclosure of a reference which mirrors the combination of requirements set forth in an applicant's claim. For obviousness under Section 103(a) it is also necessary that the reference provide some teaching or suggestion which would motivate a person of ordinary skill in the art to do what the applicant has done, that is, to make the particular selection which results in the claimed combination³). Where -as here- the reference does not provide the necessary motivating teaching or suggestion, any possible selection and combination which is possible within the generic disclosure is equally likely and the reference merely issues an invitation to make and try out each of the possible selections and combinations. "Obvious to try" is, however, not a proper basis for finding that a claimed invention is unpatentable under Section 103(a)⁴). Also, where the reference fails to provide the necessary motivating teaching or suggestion, a focus on the particular selection which results in the claimed combination is motivated by the disclosure of the applicant's invention. It is, however, hindsight when the applicant's own teaching is used against the applicant⁵), and hindsight is impermissible in a determination under Section 103(a)⁶).

While the Examiner concedes that the teaching of *Jensen et al.* is lacking because lactose is not mentioned, the Examiner takes the

3) Cf. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438, 1442 (CAFC 1991). See also *In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (CAFC 1994); *In re Jones*, 958 F.2d 347, 350, 21 USPQ2d 1941, 1943 (CAFC 1992).

4) Cf. *Merck & Co. Inc. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 10 USPQ2d 1843 (CAFC 1989) where the Court held that an invention was merely "obvious to try" if the prior art gives either no indication of which parameters are critical or no direction as to which of the many possible choices is likely to be successful.

5) Cf. *Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553, 230 USPQ 303 312-313 (CAFC 1983): "To imbue one of ordinary skill in the art with the knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein which only the inventor taught is used against the teacher."

6) Cf. *In re Dow Chemical Co.*, 837 F.2d 469, 5 USPQ2d 1529 (CAFC 1988).

position that "lactose is a well-known protein stabilizer conventionally used ... in the art" and that the respective knowledge "is evident from the reference of *Horn et al.*"⁷⁾. The teaching of *Horn et al.* provides in this regard⁸⁾ that "sugars or sugar alcohols, eg. sucrose, glucose, lactose, invert sugar, sorbitol, mannitol or glycerol", can be employed to increase the mechanical stability of swellable colloids such as "gelatin, starch, dextrin, pectin, gum arabic, casein, caseinate ... polyvinyl alcohol, polyvinylpyrrolidone, methylcellulose, carboxymethylcellulose, hydroxypropylcellulose and alginates". The disclosure of *Horn et al.* therefore, at best, provides that the enumerated sugars and sugar alcohols are equivalent in their capability to improve the mechanical stability.

As pointed out in the foregoing, a person of ordinary skill in the art learns from the teaching of *Jensen et al.*, at best, that any one of the enumerated hydrocolloids can be used in combination with any carbohydrate and that the nature of the combination has no particular impact on the colorant-preparations addressed by *Jensen et al.* The disclosure of *Horn et al.* that sugars and sugar alcohols are equally suited to improve the mechanical stability of certain swellable colloids does not add anything to the teaching of *Jensen et al.* which would motivate a person of ordinary skill in the art to focus on a particular colloid or on a particular sugar or sugar alcohol. A focus on the specific selection and combination of soybean protein and lactose can clearly not be deemed to be motivated by what the teaching of *Jensen et al.* and/or by the disclosure of *Horn et al.* convey to a person of ordinary skill in the art. A specific selection and combination of soybean protein and lactose requires the guidance which is provided by applicants' invention and is, therefore, based on hindsight.

Essentially the same applies to the Examiner's position that applicants' Claims 5 and 8 which require the use of lactose in combination with a soybean protein having a degree of hydrolysis of from 0.1 to 20% are unpatentable under Section 103(a) in light of the teaching of *Jensen et al.* (WO 91/06292) when taken in view of the disclosure of *Dobler et al.* (US WO 96/01570). The Examiner points in this context to the disclosure of *Dobler et al.* for its showing that it is known in

7) Cf. page 4, lines 17 to 20, of the Office action dated April 20, 2004 (in the following also referenced as "Paper No. 08").

8) Cf. col. 3, indicated lines 27 to 39, of US 4,522,743.

the art to employ partially hydrolyzed soybean proteins as protective colloids for fat soluble substances such as carotenoids.

However, a person of ordinary skill in the art learns from the teaching of *Jensen et al.* when taken in view of the disclosure of *Dobler et al.*, at best, that any one of the enumerated hydrocolloids -including partially hydrolyzed soybean proteins- can be used in combination with any carbohydrate and that the nature of the combination has no particular impact on the colorant-preparations addressed by *Jensen et al.* With regard to the nature of the carbohydrates the disclosure of *Dobler et al.* merely provides that conventional auxiliaries which can be employed in the preparation include *inter alia* sugars and sugar alcohols⁹⁾ such as glucose¹⁰⁾. The teaching of *Jensen et al.* taken in view of the disclosure of *Dobler et al.* would therefore not motivate a person of ordinary skill to focus on the specific selection and combination of partially hydrolyzed soybean protein and lactose.

The foregoing also applies where the patentability of applicants' Claims 1 to 15 under Section 103(a) in light of the teaching of *Dobler et al.* when taken in view of the disclosure of *Horn et al.* is concerned because *Horn et al.*'s disclosure, at best, merely provides that the enumerated sugars and sugar alcohols "*sucrose, glucose, lactose, invert sugar, sorbitol, mannitol or glycerol*" are equivalent in their capability to improve the mechanical stability.

Overall, the teachings of *Jensen et al.*, *Dobler et al.* and *Horn et al.* convey to a person of ordinary skill in the art that powders comprising a fat soluble colorant such as a carotenoid can be obtained when

- a₁) a hydrocolloid including "*extrudates, such as gum arabic, tragacanth, gum karaya, gum ghatti; extracts from seaweed, such as agar, alginate, carrageenan and furcellaran; extracts from plants, such as pectin and arabinogalactan; extracts from marine and terrestrial animals, such as gelatines and other proteinaceous hydrocolloids, flours from seeds, such as guar, locus bean, soy bean; proteins from seeds, such as soya bean protein; flours from cereals, such as starches and microcrystalline cellulose; biosynthetic or fermentation derived hydrocolloids, such as cellulose derivatives, including methyl cellulose, and other deriva-*

9) Cf. page 4, indicated lines 6 to 11, of WO 96/01570.

10) Cf. the Examples summarized on pages 5 to 7 of WO 96/01570.

tives, including modified starches and low methoxy pectin; synthetic hydrocolloids, such as polyvinylpyrrolidon, carboxyvinyl polymers, etc."¹¹⁾; or

- a₂) "partially degraded soybean proteins which preferably have a degree of degradation ... of 0.1 to 5% ..." ¹²⁾; or
- a₃) swellable colloids such as "gelatin, starch, dextrin, pectin, gum arabic, casein, caseinate ... polyvinyl alcohol, polyvinylpyrrolidone, methylcellulose, carboxymethylcellulose, hydroxypropylcellulose and alginates" ¹³⁾,

are employed as "protective" colloid, and

- b₁) "dissolved carbohydrate, such as sorbitol and sucrose", is used as excipient ¹⁴⁾; or
- b₂) "sugars or sugar alcohols, starch or starch derivatives, stabilizers ... as well as emulsifiers ..." are used as conventional auxiliaries ¹⁵⁾; or
- b₃) "sugars or sugar alcohols, eg. sucrose, glucose, lactose, invert sugar, sorbitol, mannitol or glycerol", are employed to increase the mechanical stability of swellable colloids ¹⁶⁾.

Based on those teachings, a person of ordinary skill in the art would reasonably expect that a preparation which comprises one of the "protective" colloids enumerated in (a₁) to (a₃) in combination with one of the sugars or sugar alcohols enumerated in (b₁) to (b₃) has essentially the same properties as a preparation which comprises the same or a different colloid in combination with a different sugar or sugar alcohol.

Applicants' data show that the expectation is not met when the "protective" colloid is a soybean protein. More particularly, applicants' data show that the preparation which is obtained when the

11) Cf. the teaching of *Jensen et al.* on page 4, indicated line 35, to page 5, indicated line 9, of *WO 91/06292*.

12) Cf. the teaching of *Dobler et al.* on page 3, indicated lines 4 to 7, of *WO 96/01570*.

13) Cf. the teaching of *Horn et al.* in col. 3, indicated lines 27 to 32, of *US 4,582,743*.

14) Cf. the teaching of *Jensen et al.* on page 5, indicated lines 19 to 22, of *WO 91/06292*.

15) Cf. the teaching of *Dobler et al.* on page 4, indicated lines 6 to 11, of *WO 96/01570*.

16) Cf. the teaching of *Horn et al.* in col. 3, indicated lines 35 to 39, of *US 4,582,743*.

soybean protein is employed in combination with lactose has distinctly improved properties when compared with a preparation which is obtained when the soybean protein is employed in combination with glucose as exemplified by *Dobler et al.*¹⁷⁾.

With regard to applicants' invention the teaching of *Dobler et al.* constitutes the closes prior art because the exemplified representatives disclosed by *Dobler et al.* differ from applicants' invention solely in the nature of the sugar. The representative examples provided by *Jensen et al.* and by *Horn et al.* differ from applicants' invention in two aspects, namely in the nature of the protective colloid and in the nature of the sugar¹⁸⁾. A comparison of applicants' invention with the examples of *Jensen et al.* and/or *Horn et al.* would therefore not yield results which are of probative value. Also, since the examples of *Jensen et al.* and/or *Horn et al.* are further away from applicants' invention than the examples disclosed by *Dobler et al.*, a comparison with the examples of *Jensen et al.* and/or *Horn et al.* is not deemed to be necessary.

The Examiner has criticized applicants' respective previous remarks¹⁹⁾ as non-persuasive, arguing that "there are no claims present that represent the scope of the showing presented"²⁰⁾. However, it is well settled that the non-obviousness of a broader claimed range can be supported by evidence based on unexpected results from testing a narrower range if one of ordinary skill in the art would be able to reasonably extend the probative value of the data to the range of the claims²¹⁾. In the present case, a person of ordinary skill in the art can reasonably extend the probative value of applicants' data to the range of applicants' claims because, based on the pertinent art represented by the teachings of *Dobler et al.*, *Jensen et al.* and *Horn et al.*, a person of ordinary skill can reasonably expect

- that all carotinoids will behave in the context of applicants' invention in the same manner as the representatives which were employed by applicants in their investigations, and
- that all soybean proteins will behave in the context of applicants' invention in the same manner as the representatives which

17) Applicants' reply dated January 20, 2004 (in the following also referenced as "Paper No. 07").

18) Cf. MPEP §716.02(e) subsection III., page 700-263 (Rev. 2, May 2004).

19) Applicants' Paper No. 07.

20) Cf. page 10, lines 7 to 11, of Paper No. 08.

21) Cf. *In re Kollman*, 595 F.2d 48, 201 USPQ 193 (CCPA 1979).

were employed by applicants in their investigations.

In light of the foregoing and in light of the arguments already presented by applicants in the earlier proceedings²²⁾ it is respectfully requested that

- the rejection of Claims 1 to 4, 6, 7 and 9 to 15 based on the teaching of *Jensen et al.* when taken alone or when taken in view of the disclosure of *Horn et al.*;

- the rejection of Claims 5 and 8 based on the teaching of *Jensen et al.* when taken in view of the disclosure of *Dobler et al.*; and

- the rejection of Claims 1 to 15 based on the teaching of *Dobler et al.* when taken alone or when taken in view of the disclosure of *Horn et al.*;

be withdrawn. Favorable action is solicited.

REQUEST FOR EXTENSION OF TIME:

It is respectfully requested that a three month extension of time be granted in this case. A check covering the \$950.00 fee is enclosed with the request for continued examination.

Please charge any shortage in fees due in connection with the filing of this paper, including Extension of Time fees, to Deposit Account No. 11.0345. Please credit any excess fees to such deposit account.

Respectfully submitted,

KEIL & WEINKAUF



Herbert B. Keil

Reg. No. 18,967

1350 Connecticut Ave, N.W.
Washington, D.C. 20036
(202) 659-0100

Encl.: THE LISTING OF CLAIMS (Appendix I)

HBK/BAS

²²⁾ Applicants' Paper No. 07.